N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-fluorophenyl)-(2-nitrophenyl)methanesulfonamide; and

N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-fluorophenyl)-2,5-dibromo-3,6-difluoro-1-benzenesulfonamide;

and pharmaceutically acceptable salts thereof.

47. The compound of Claim 1, wherein L is $-NHSO_2-$ or -NHC(O)-.

48. The compound of Claim 1, wherein L is $-NHSO_2CH_2-$, $-NHC(O)CH_2-$, or $-NHSO_2CH=CH-$.

REMARKS

The remainder of this Amendment is set forth under appropriate subheadings for the convenience of the Examiner.

I. Claim Amendments

In order to clarify that the variable "R" in the groups "-NHC(O)R-" and "$-NHSO_2R-$" of Claim 11 is a divalent aliphatic group, Applicants have amended Claim 1 to add "$-NHC(O)R_{130}-$" and "$-NHSO_2R_{130}-$", wherein $R_{130}$ is an aliphatic group, to the list of groups suitable for L. Applicnats have amended Claim 11 to correspond with Claim 1. In addition, Applicants have added Claim 47 in which L is $-NHSO_2-$ or -NHC(O)-. Antecedent basis for Claim 47 can be found in Claim 1 where L can be $-NRSO_2-$ or -NRC(O)- and R can be H. Claim 48 has also been added wherein L is $-NHSO_2CH_2-$, $-NHC(O)CH_2-$, and $-NHSO_2CH=CH-$. Support for this amendment can be found in Examples 185-187 on page 174 of the specification and Examples 290-294 on pages 205-208 of the specification.

Applicants have amended Claim 1 by replacing "and" in the phrase "and pharmaceutically acceptable salts" with "or" to indicate that a compound is claimed, not a mixture of compounds.

Applicants have amended a typographical error in Claim 4 by replacing "threnyl" with "thienyl". Support for this amendment can be found in Examples 302-317 on pages 210-212 of the specification and in Examples 323 and 324 on page 214 of the specification.

Applicants have cancelled Claim 9 and redrafted it as Claim 46 in which "1", "2", "3" and "4" have been removed from the terms "N1", "N2", "N3", and "N4", respectively, because the numbers are redundant. In addition, Applicants have remove the species N1-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl)-1-benzenesulfonamide from redrafted Claim 46.

II. Rejection of Claims 1-45 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 1-45 under 35 U.S.C. § 112, first paragraph because the Examiner believes that the specification does not enable a person skilled in the art to prepare or to use all of the claimed compounds. Specifically, the Examiner has stated that for many of the claim terms, such as "aliphatic", "aromatic", heteroaromatic", etc., there is no explanation of the size or nature of the group. In addition, the Examiner has stated that the scope of the term "substituted" is unclear and that Applicants have not disclosed essential starting materials needed to prepare the instantly claimed compounds having "substituted" groups such as "aliphatic" and "heteroaromatic" groups. The Examiner has stated that the specification does not enable one skilled in the art to use the claimed compounds because the Examiner does not feel that preparation of the instantly claimed compounds is enabled or that the exemplified compounds are representative of all the possible compounds encompassed by the claims.

On page 22, line 17 to page 23, line 12 of the specification, Applicants provide explanations for the terms "aromatic", "heteroaromatic", "aralkyl", "heteroaralkyl", "heterocycloalkyl", "acyl" and "aliphatic" groups. These explanations provide guidance for the size and nature of these groups. For example, aliphatic groups typically have 1-8 carbon atoms; aralkyl and heteroaralkyl groups are linked to a compound by an aliphatic group having from 1-6 carbon atoms; and heterocycloalkyl groups have 3-8 atoms. In addition, many examples of suitable aromatic and heteroaromatic ring systems are provided. Therefore, the definitions of the terms "aromatic", "heteroaromatic", "aralkyl", "heteroaralkyl", "heterocycloalkyl", "acyl" and "aliphatic" groups provide an explanation of the size and nature of these groups.

On page 22, lines 5-14, Applicants have provided a non-limiting list of exemplary substituents for substituted aromatic or heteroaromatic groups of ring A. On page 20, line 24 to page 21, line 3, Applicants have provided a non-limiting list of exemplary substituents for substituted cycloalkyl, aromatic, heteroaromatic, heterocycloalkyl, alkyl, alkenyl or aralkyl groups of $R_3$. These substituent lists provide representative substituents from which a person skilled in the art could determine suitable substituents for ring A and $R_3$. In addition, a person skilled in the art could determine the number of substituents a particular group could have since the number is self-limiting. For example, a phenyl group can have from zero to five substituents.

A person skilled in the art would be able to prepare Applicants' claimed compounds using the methods disclosed in the specification. For example, on page 60, line 26 to page 61, line 15 of the specification, Applicants provide a method of preparing a compound of Structural Formula I by condensing a 2-amino-3-cyano-4-(ring A)-pyrrole precursor with formamide at elevated temperatures. In Scheme I, on page 67 of the specification, Applicants provide a method of forming the 2-amino-3-cyano-4-(ring A)-pyrrole precursor from ring A which is substituted with an α-bromoketone, for example from an α-bromoacetylphenone (i.e., $R_2$ is -H and ring A is phenyl). Bromination at the α-position to a carbonyl group is known in the art and can be achieved by contacting compound having a carbonyl group with bromine in the presence of an acid or a basic catalyst (see Exhibit A, Kemp and Vellaccio, *Organic Chemistry*, Worth Publishers, Inc., N.Y. (1980), pages 808-809). This method allows a person skilled in the art to prepare the compounds of the invention from simple starting materials which are commercially available or can be synthesized by reactions known to those skilled in the art. For example, acetylphenone and many other acetyl substituted heteroaromatic compounds (e.g., acetyl pyrazine, acetylpyridine, acetylpyrrole, acetylthiazole, acetyl thiophene, and acetylfuran) can be purchased from Aldrich (see Exhibit B, Aldrich Chemical Catalog, 1996-1997, pages 18, 19 and 24-26) and brominated by the method described in Exhibit A. Once the position α to the carbonyl has been brominated the 2-amino-3-cyano-4-(ring A)-pyrrole precursor can be constructed by the method of Scheme I.

Before bromination, the ketone group can be protected, if necessary, and substituents can be added to an aromatic or heteroaromatic ring A by methods known to those skilled in the art. For example, benzene is known to undergo electrophilic substitution with a variety of

electrophiles to add a variety of substituents (see Exhibit C, Kemp and Vellaccio, *Organic Chemistry*, Worth Publishers, Inc., N.Y. (1980), page 706, Chart 20-1). In addition, a nitro substituent can be converted into an amine group. An amine substituent can be converted to a diazonium salt which can be converted into a number of different substituents (see Exhibit C, *Id.*, page 736, Figure 21-1). A pyridine can be substituted with a halogen by forming the N-oxide then treating it with the halogen in the presence of $Ag_2SO_4$ or $H_2SO_4$. The halogen substituent can converted to a hydroxyl group by heating the compound in the presence of water. Alternatively, the halogen can be converted to an amine by heating the halopyridine with sodamide (see Exhibit C, *Id.*, page 1236, paragraph 1 to page 1237, paragraph 2). Pyrroles can undergo substitution reactions with electrophilic reagents to add halo, aldehyde or ketone substituents (see Exhibit C, *Id.*, page 1238, paragraphs 1 and 2). Furans can be nitrated with nitric acid in acetic acid. The nitro group can be reduced to form an amine group. Furans can also undergo addition reactions to form alkoxy derivatives (see Exhibit C, *Id.*, page1237, paragraph 2 to page 1238, paragraph 1). Thiophenes can undergo electrophilic substitution similar to benzene (see Exhibit C, *Id.*, page 1237, paragraph 2).

In addition to the general method of making compounds represented by Structural Formula I, Applicants have provided methods of making 324 representative compounds of the invention. The extensive experimental section provides examples in which ring A is a phenyl (see Examples 1-7, 9, 11-22, 24-159, 161, 163-166, and 168-324), a pyridyl (see Examples 10, 23 and 177), an indolyl (see Example 162), and a 2,3-dihydro-1H-indolyl (see Example 8). In addition, the experimental section also provides examples wherein $R_3$ is a substituted or unsubstituted phenyl (see Examples 1-3, 6-12, 14, 20, 21-25, 27-33, 35-158, 176-186, 188-191, 193-213, 215-217, 220-239, 241-244, 246-258, 260, 262-284, 290, and 292-296), substituted or unsubstituted aliphatic (see Examples 17, 287, 288, and 289), substituted or unsubstituted cycloalkyl (see Examples 19 and 291), substituted or unsubstituted pyridyl (see Examples 4, 5, 13, 18, and 321), substituted or unsubstituted thienyl (see Examples 34, 187, 286, 302-307, 309-317, 323 and 324), substituted or unsubstituted naphthyl (see Examples 192, 219, 240, 259 and 261), substituted tetrahydroisoquinoline (see Example 214), quinoline (see Example 245), substituted or unsubstituted benzothiadiazole (see Examples 285 and 319), substituted imidazole (see Examples 297 and 308), substituted pyrrazole (see Example 298), substituted isoxazole (see

Example 299), substituted pyrrole (see Example 300) and substituted or unsubstituted bezoxadiazole (see Examples 320 and 322).

With regard to the use of the compounds, Applicants have stated that the compounds represented by Structural Formula I inhibit tyrosine and serine/threonine kinases (see page 19, lines 15-18 of the specification). Applicants have described how the inhibition of tyrosine and serine/threonine kinases is related to alleviation or prevention of various disease states (see page 27, line 8 to page 36, line 9 of the specification). Moreover, Applicants have provided methods of using the claimed compounds to treat disorders or conditions mediated by protein kinases (see page 37, line 1 to page 46, line 23 of the specification) and methods of determining the potency of the claimed compounds (see page 46, line 24 to page 60, line 15 of the specification).

The court in *In re Marzocchi* stated that:

> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing an defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support. *In re Marzocchi & Horton*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in the original).

In the instant application, Applicants have disclosed a method of forming compounds represented by Structural Formula I from aromatic or heteroaromatic ketones which can be substituted with a wide variety of substituents by methods known in the art. Applicants have provided 324 examples of methods of preparing a variety of substituted and unsubstituted compounds represented by Structural Formula I. Applicants have stated that compounds represented by Structural Formula I inhibit protein kinases, which are associated with various disease states, and have provided methods of determining the potency of these compounds. Moreover, the Examiner has provided no reason to doubt Applicants' assertion that the claimed

compounds inhibit protein kinases. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

III. Rejection of Claims 1-45 Under 35 U.S.C. 112, Second Paragraph

A. The term "substituted"

The Examiner has stated that the term "substituted" which modifies aliphatic, aromatic, heteroaromatic, etc. in Claims 1-7 renders unclear the nature and number of substituents intended.

As described above, on page 22, lines 5-14, Applicants have provided a representative list of suitable substituents for ring A. On page 20, line 24 to page 21, line 3, Applicants have provided a representative list of suitable substituents for $R_3$. From these substituent lists, one skilled in the art could determine the scope of the term "substituted". Moreover, Applicants have disclosed numerous specific examples of substituted aliphatic, aromatic, heteroaromatic, etc. in the experimental section of the application.

B. The phrase "and pharmaceutically acceptable salts"

The Examiner has stated that the phrase "and pharmaceutically acceptable salts" in Claim 1 is indefinite because it is not clear whether compounds or a mixture of compounds and the corresponding salt is claimed.

Applicants have amended Claim 1 to substitute "or" for "and" in the phrase "and pharmaceutically acceptable salts" to indicate that compounds are claimed, not a mixture of compounds and their corresponding salts.

C. The term "N1"

The Examiner has stated that the "1" in the term "N1" is redundant in the species claimed in Claim 9.

To correct the redundancy, Applicants have cancelled Claim 9 and redrafted it as Claim 46 in which the "1" following "N" in each species has been removed. In addition, in Claim 46, Applicants have removed "2", "3" and "4" where they appear in the terms "N2", "N3" and "N4", respectively.

D. Antecedent basis for "-NHC(O)R-" and "-$NHSO_2R$-" in Claim 11

The Examiner has stated that there is no antecedent basis for the limitation "-$NHSO_2R$-" and "-NHC(O)R-" in Claim 11.

Applicants have amended Claim 11 to replace "-NHC(O)R-" and "-$NHSO_2R$-" with "-$NHC(O)R_{130}$-" and "-$NHSO_2R_{130}$-", respectively. Applicants have also amended Claim 1 to add -$NHC(O)R_{130}$- and -$NHSO_2R_{130}$- to the list of groups suitable for "L", thus providing antecedent basis for the terms "-$NHC(O)R_{130}$-" and "-$NHSO_2R_{130}$-" in Claim 11.

As originally filed, the definition of "R" includes aliphatic groups, and Claim 11 as originally filed, indicates that Applicants considered "R" in the groups "-NHC(O)R-" and "-$NHSO_2R$-" to be a divalent group since it has two bonds. Therefore, in order to clarify that the variable "R" in the groups "-NHC(O)R-" and "-$NHSO_2R$-" of Claim 11 is a divalent aliphatic group, Applicants have amended Claim 1 to add "-$NHC(O)R_{130}$-" and "-$NHSO_2R_{130}$-", wherein $R_{130}$ is an aliphatic group, to the list of groups suitable for L and have amended Claim 11 to correspond with Claim 1.

E. The term "prodrug"

The Examiner has stated that the term "prodrug" in Claims 12, 16 and 39 is indefinite because they are neither specified nor would they be apparent to one of ordinary skill in the art.

The term "prodrug" is a term of art the meaning of which would be apparent to one of ordinary skill in the art. For example, the term "prodrug" is defined in *Stedman's Medical Dictionary* as "A class of drugs the pharmacologic action of which results from conversion by metabolic processes within the body (biotransformation)" (See Exhibit D, *Stedman's Medical Dictionary*, 24th Edition, Williams & Wilkins, Baltimore, Maryland (1982), page 1144). Thus, compounds which can metabolize to form a compound of Claim 1 are prodrugs. Since the definition of "prodrug" is known to those skilled in the art, Claims 12, 16 and 39 are not indefinite.

F. Antecedent basis for the conditions listed in Claim 33

The Examiner has stated that there is insufficient antecedent basis for the conditions mediated by a protein kinase listed in Claim 33 because Claim 32 on which Claim 33 depends limits the condition mediated by a protein kinase to a cardiovascular condition.

The term "cardiovascular" means "Relating to the heart and the blood vessels or circulation" (see Exhibit E, *Stedman's Medical Dictionary*, 24th Edition, Williams & Wilkins, Baltimore, Maryland (1982), page 227). The conditions listed in Claim 33 which are mediated by a protein kinase are atherosclerosis, restenosis, ischemia/reperfusion injury, vascular occlusion, venous malformation, or carotid obstructive disease. All of these conditions are related to the heart, blood vessels or circulation. Therefore, Claim 32 provides sufficient antecedent basis for the conditions listed in Claim 33.

IV. Rejection of Claims 1-45 Under 35 U.S.C. § 102(e) Over U.S. Patent No. 6,001,839

The Examiner has rejected Claims 1-45 under 35 U.S.C. § 102(e) as being anticipated by Calderwood, *et al.*, U.S. Patent No. 6,001,839 (hereinafter "'839") which has an effective filing date of March 19, 1997. The Examiner has stated that the claimed compounds read on the compounds of the reference, and that the species in Claim 9 is identically disclosed.

The present situation is analogous to that at issue in *Applied Materials Inc v. Gemini Research Corp.*, 15 U.S.P.Q.2d 1817 (Fed. Cir. 1988). In that case, the Court of Appeals determined that U.S. Patent No. 3,623,712 (hereinafter "'712") could not be used as prior art under 35 U.S.C. § 102(e) against a continuation-in-part application, U.S. Patent No. 4,081,313 (hereinafter "'313") which grew out of the same original application and which had the same inventorship plus one additional inventor. In reversing the ruling by the district court that the '313 patent was invalid because of anticipation under 35 U.S.C. § 102(e), the Court of Appeals stated the following:

> When the 102(e) reference patentee ['712] . . . had knowledge of the joint applicants' invention ['313] by being one of them, and *thereafter* describes it, he necessarily files the application ['712] *after* the ['313] applicant's invention date. . . . Thus, the district court erred because its invalidity decision was based on the incorrect premise that the '712 patent was 102(e) prior art against

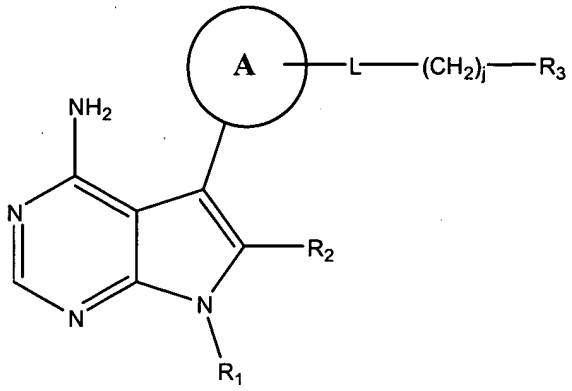
> the '313 patent" (emphasis in the original). *Applied Materials Inc. v. Gemini Research Corp.*, 15 U.S.P.Q.2d 1817, 1818.

The instant patent application claims priority to '839 under 35 U.S.C. § 120, and both '839 and the instant application claim the benefit of U.S. Provisional Application No. 60/040,836 under 35 U.S.C. § 119(e). The instant application and '839 have six inventors in common and these six inventors comprise the inventorship of '839. Therefore, as in *Applied Materials Inc. v. Gemini Research Corp.*, if the patentee of '839 had knowledge of the instant invention by being one of the inventors of the instant invention, and described the instant invention in the '839 patent, he must have invented the instant invention before the filing date of the '839 patent. Under 35 U.S.C. § 102(e), Applicants' invention is precluded only if the invention was described in a patent by another filed in the United States *before the invention* by the Applicants. In the instant case, the subject invention would have had to be invented before the filing of '839 if it was fully described therein, and then by an inventor of the instant application. Therefore, '839 cannot be used a §102(e) prior art against the subject invention.

V. Rejection of Claims 1-8 and 10-45 Under 35 U.S.C. § 103(a) Over WO96/10028

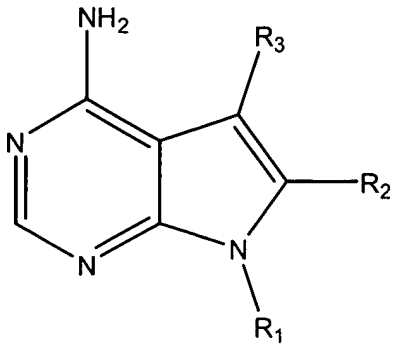
The Examiner has rejected Claims 1-8 and 10-45 under 35 U.S.C. § 103(a) over Missbach, WO96/10028 (hereinafter "Missbach") because in the Examiner's opinion, the reference teaches a generic group of compounds which embrace Applicant's claimed compounds and which are taught to be useful as protein tyrosine kinase inhibitors. The Examiner has stated that "[o]ne of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole."

Applicants claim a genus of compounds and methods of using compounds represented by the following structural formula:




In the above structural formula, Ring A is an optionally substituted six membered aromatic ring or an optionally substituted five or six membered heteroaromatic ring. L is a linking group (see Claim 1 for further details.) $R_1$ is -H, 2-phenyl-1,3-dioxan-5-yl, a C1-C6 alkyl group, a C3-C8 cycloalkyl group, a C5-C7 cycloalkenyl group or an optionally substituted phen(C1-C6 alkyl) group. The alkyl, cycloalkyl and cycloalkenyl groups of $R_1$ can be optionally substituted with a one or more substituents selected from hydroxyl, a C1-C6 alkoxy or a C3-C6 cycloalkoxy group. $R_2$ is -H, a halogen, -OH, cyano, $-NR_4R_5$, $-C(O)NR_4R_5$, or an optionally substituted aliphatic, cycloalkyl, aromatic, heteroaromatic, heterocycloalkyl, aralkyl or heteroaralkyl group. $R_3$ is an optionally substituted cycloalkyl, aromatic, heteroaromatic or heterocycloalkyl group; or $R_3$ is an optionally substituted alkyl, alkenyl or aralkyl group when L is $-NRSO_2-$, -NRC(O)-, -NRC(O)O-, $-S(O)_2NR-$, -C(O)NR- or -OC(O)NR- (see Claim 1 for further description of substituents and for alternative definitions of $R_3$).

Missbach teaches compounds that inhibit protein tyrosine kinase $pp60^{c\text{-}src}$ (see Missbach, Abstract). The compounds taught by Missbach have the following structural formula:




in which $R_1$ is an aryl; $R_2$ is hydrogen, lower alkyl or a halogen; and $R_3$ is an aryl (see Missbach, page 1, lines 2-6). Missbach defines the term "aryl" as phenyl or naphthyl and further states that the aryl can be substituted with a variety of groups (see Missbach, page 2, line 8 to page 4, line 2). Missbach teaches a number of preferred embodiments which all have $R_1$ equal to a substituted or unsubstituted phenyl (see Missbach, page 7, line 13 to page 12, line 7). In addition, in all of the Examples disclosed by Missbach, $R_1$ is a substituted or unsubstituted phenyl (see Missbach, Examples 1-178, page 23, line 21 to page 64, line 10).

Applicants' claimed compounds are not embraced by the genus disclosed by Missbach. In the genus disclosed by Missbach, $R_1$ is a substituted or unsubstituted phenyl or naphthyl. Missbach's genus does not include Applicants' claimed compounds in which $R_1$ is -H, 2-phenyl-1,3-dioxan-5-yl, a C1-C6 alkyl group, a C3-C8 cycloalkyl group, a C5-C7 cycloalkenyl group or an optionally substituted phen(C1-C6 alkyl) group, wherein alkyl, cycloalkyl and cycloalkenyl groups can be optionally substituted with a hydroxyl, a C1-C6 alkoxy or a C3-C6 cycloalkoxy group. Therefore, the compounds disclosed by Applicants are not a subgenus of the genus disclosed by Missbach.

Missbach provides no motivation to modify his disclosed genus to obtain Applicants' claimed compounds. The preferred embodiments and examples which Missbach teaches all have $R_1$ equal to substituted or unsubstituted phenyl. Missbach does not teach or suggest that $R_1$ could be any of the moieties which Applicants disclose as $R_1$. Therefore, a person of ordinary skill in the art would have no motivation to modify the genus disclosed by Missbach to obtain

Applicants' claimed compounds. Thus, Applicants request that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

VI. Rejection of Claims 1-45 Under 35 U.S.C. § 103(a) Over U.S. Patent No. 6,001,839

The Examiner has rejected Claims 1-45 under 35 U.S.C. § 103(a) over Calderwood, *et al.*, U.S. Patent 6,001,839 because the Examiner observed that the reference teaches a generic group of compounds which embrace Applicants' instantly claimed compounds, and the reference teaches that the compounds are useful as therapeutic agents having protein kinase inhibitory activity. The Examiner has stated that the instant claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, the Examiner felt that it would be obvious to one of ordinary skill in the art to select any of the species of the genus taught by the reference.

The instant application is a continuation-in-part of Calderwood. Applicants have amended the specification to claim the benefit of U.S. Provisional Application No. 60/040,836, filed on March 19, 1997. Therefore, the instant application has the same effective filing date as Calderwood for subject matter which overlaps with the subject matter of Calderwood.

The subject matter of the instant application which does not overlap with the subject matter of Calderwood is non-obvious.

VII. Non-Statutory Double Patenting Rejection

The Examiner has rejected Claims 1-45 under the judicially created doctrine of double patenting over Claims 1-27 of Calderwood because the Examiner feels that the reference patent claims an invention with common subject matter to that of the instantly claimed invention. In addition, the Examiner has stated that Claim 24 of Calderwood includes one of the compounds that is instantly claimed in Claim 9.

The Examiner has also rejected Claims 1-45 under the judicially created doctrine of obviousness-type double patenting over Claims 1-27 of Calderwood.

Applicants have cancelled Claim 9 and redrafted it as Claim 46. The species N1-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl)-1-benzenesulfonamide which was claimed in Calderwood has been removed from Claim 46.

Applicants' instant invention is not fully disclosed in and covered by Claims 1-27 in Calderwood. Therefore, the instant application does not violate the judicially created doctrine of double patenting or the judicially created doctrine of obviousness-type double patenting in view of Calderwood.

## CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,

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